California Medical Device Recall Information

Recall Name
Stryker Orthopaedics Recalls ShapeMatch Cutting Guides Due to the Potential that Guides Were Not Manufactured Per Surgeon Parameters

Recall Date	Product Description	Recalling Firm	Recall Reason
4/10/13	**ShapeMatch Cutting Guides** • Custom, patient-specific surgical instrumentation for total knee replacement surgery.	**Stryker Orthopaedics / Stryker Howmedica Osteonics Corp.** Mahwah, NJ	*Defects in production software resulted in adulterated and unapproved surgical guides that when used as intended potentially results in serious adverse health consequences.*
Recall Class	**Product Identification**	**Distribution**	**Affected Dates**
I	Catalog Numbers: • **TR7100-R** • **TR7100-L** [NOTE: The *Triathlon Knee System* and *Triathlon* standard instrumentation are not affected by the recall.]	**CA**, nationwide	Manufactured and distributed from: May 2011 to November 2012.

FOR ADDITIONAL INFORMATION, PLEASE VISIT:

http://www.fda.gov/Safety/Recalls/ucm347552.htm

http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm348536.htm